1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities for ensuring that *conditions adverse to quality* (see def.) are promptly identified and corrected as soon as practical through the company's Corrective Action System. See Appendix A for requirements basis.

2. APPLICABILITY

This PRD applies to company organizations and subcontractors responsible for achieving, maintaining, and verifying the quality of items, services, and activities of facilities, programs, and projects; and to those corresponding conditions that may be adverse to safety, health, operations, quality, security (except as noted below), and the environment.

This PRD applies to conditions identified by external agencies or by employees during internal independent assessments; *management assessments* (see def.) and *surveillances* (see def.); manufacturing, installation, and *testing* (see def.) activities; operations, and maintenance activities; and normal work assignments.

NOTE: *The Issue Communication and Resolution Environment (ICARE) system is the approved company system for tracking conditions adverse to quality.*

This PRD does not apply to reporting and resolving *employee concerns* (see def.); protective services' assessments, other than those involving environmental, safety, health and quality aspects; or processing improvement suggestions.

3. RESPONSIBILITIES

3.1 Senior Management

Senior management is responsible for:

A. Ensuring that *corrective action* (see def.) system requirements are implemented.

B. Establishing and communicating the standards for regulatory compliance.

3.2 Quality Assurance Organization

The quality assurance organization is responsible for providing overall leadership for the company's quality assurance program and corrective action/ issues management process.

3.3 Performance Assurance Organization

The performance assurance organization is responsible for definition, development, implementation, and oversight of the Issues Management Program and Corrective Action System.

3.4 Cognizant Director or Designee (Site-Area, Functional, and Program)

The cognizant director or designee is responsible for:

A. Ensuring that company-level procedures and systems relating to the Issues Management Program and Corrective Action System are effectively implemented.

B. Promoting an open environment and culture to support identification and resolution of issues and conditions adverse to quality.

C. Being accountable and responsible for ensuring that conditions adverse to quality (see def.) affecting the site-area, program, or functional areas under their purview are identified, documented, and resolved in an effective and timely manner.

D. Using designees to implement many of the activities to resolve conditions adverse to quality and ensuring that adequate priority and resources are allocated for effective program implementation.

E. Performing categorization and classification evaluations to determine their type and significance.

F. Approving corrective action plans, schedules, and revisions thereto, which involve *significant conditions adverse to quality* (see def.).

G. Ensuring that applicable lessons learned information is shared as appropriate, follow-up assessments are performed, and trend analysis is conducted to identify other conditions adverse to quality or recurrence of previously closed conditions.

3.5 Responsible Manager or Designee

The *responsible manager* (see def.) or designee is responsible and accountable to the cognizant director to ensure that the following elements of the program are implemented:

A. Proper notification or reporting is completed.

B. Appropriate cause analysis is performed and documented by a qualified analyst.

C. Corrective action plans address identified cause(s).

D. Corrective action plans, revisions, and schedules for conditions adverse to quality are approved.

E. Corrective actions are implemented as scheduled or, rescheduled, if necessary.

F. All necessary documentation supporting corrective action closure is maintained as a quality record.

G. Appropriate *verification* (see def.) activities are performed.

H. Status of the item in the ICARE tracking system is current.

3.6 Lessons Learned Coordinators (Site-Area, Functional, and Program)

The lessons learned coordinators are assigned by their respective cognizant directors and are responsible for providing an interface between the local lessons learned activities and the company level Lessons Learned System Office. Site-area coordinators are also to serve as points of contact for site-area Operations Safety Boards on lessons learned items.

3.7 DOE/RW-0333P Quality Engineers

Quality engineers, who are qualified to DOE/RW-0333P requirements, are responsible for conducting concurrence reviews of all corrective action plans, including remedial action, and performing verification of corrective action plan implementation for all DOE/RW-0333P conditions.

3.8 Independent and Knowledgeable Persons

Assigned independent and knowledgeable persons are responsible for verifying implementation of corrective action plans for non-DOE/RW-0333P significant conditions adverse to quality.

3.9 Employees

Employees are responsible for identifying and reporting potential conditions adverse to quality.

4. REQUIREMENTS

4.1 Companywide Applications

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

4.1.1 Basic

4.1.1.1 Conditions adverse to quality shall be identified promptly and corrected as soon as practical. *[NQA-1-1997, Requirement 16, 100 1s]*

4.1.1.2 In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action shall be taken to preclude recurrence. *[NQA-1-1997, Requirement 16, 100 2s]*

4.1.1.3 Managers responsible for an activity shall evaluate significant conditions adverse to quality and initiate a stop work order if warranted. *[Company Imposed Requirement]*

4.1.1.4 QA management shall retain a right to initiate a stop work order for significant conditions adverse to quality in any company operation. *[Company Imposed Requirement]*

4.1.2 Classification of Conditions Adverse to Quality

4.1.2.1 Conditions adverse to quality shall be classified in regard to their significance, and corrective actions shall be taken accordingly. *[DOE/RW-0333P 16.2.2.A]*

4.1.2.2 Two categories of classification shall be established *[DOE/RW-0333P 16.2.2.B]*:

A. Conditions adverse to quality. *[DOE/RW-0333P 16.2.2.B.1]*

B. Significant conditions adverse to quality. *[DOE/RW-0333P 16.2.2.B.2]*

4.1.3 Conditions Adverse to Quality

4.1.3.1 Conditions adverse to quality shall be documented and reported to the appropriate levels of management responsible for the conditions and to the Quality Assurance (QA) organization for tracking. *[DOE/RW-0333P 16.2.3.A]*

4.1.3.2 Responsible management shall perform investigative action to determine the extent of the adverse condition and complete remedial action as soon as practical. *[DOE/RW-0333P 16.2.3.B]*

4.1.4 Significant Conditions Adverse to Quality

4.1.4.1 Criteria for determining a significant condition adverse to quality shall be established. *[DOE/RW-0333P 16.2.4.A]*

4.1.4.2 The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management responsible for the organization and to the QA organization for tracking. *[NQA-1-1997, Requirement 16, 100 3s; DOE/RW-0333P 16.2.4.B]*

4.1.4.3 Responsible management shall:

A. Perform investigative action to determine the extent and impact of the condition, and document the results. *[DOE/RW-0333P 16.2.4.D]*

B. Determine, document, and complete *remedial action* (see def.) as soon as practical. *[DOE/RW-0333P 16.2.4.E.1s]*

C. Determine the *root cause* (see def.) of the problem and take corrective action to prevent recurrence as soon as practical. *[DOE/RW-0333P 16.2.4.E.2s]*

4.1.5 Follow-up and Closure Action

4.1.5.1 Completion of corrective actions shall be verified. *[NQA-1-1997, Requirement 16, 100 4s]*

4.1.6 Quality Trending

4.1.6.1 The QA organization shall establish criteria for determining adverse quality trends. *[DOE/RW-0333P 16.2.6.A]*

4.1.6.2 Reports of *nonconformances* (see def.) and conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes. *[DOE/RW-0333P 16.2.6.B]*

4.1.6.3 Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. *[DOE/RW-0333P 16.2.6.C]*

4.1.6.4 Trend evaluations shall be distributed to impacted organizations management. *[DOE/RW-0333P 16.2.6.D]*

4.1.6.5 Identified adverse trends shall be reported to the management of the organization responsible for corrective action. *[DOE/RW-0333P 16.2.6.E]*

4.1.7 Records

4.1.7.1 All records designated in implementing documents *as quality assurance records* (see def.). shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. *[Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and company imposed requirements]*

4.2 Specific Requirement for DOE/RW-0333P QARD Revision 10 Application

This subsection (4.2) contains additional requirements from the QARD (DOE/RW-0333P, Revision 10) which are specific to the INEEL Spent Nuclear Fuel Program.

4.2.1 Identifying Conditions Adverse to Quality

4.2.1.1 A condition adverse to quality shall be identified when the Quality Assurance Requirements and Description (DOE/RW-0333P) or an implementing document requirement is not met. *[DOE/RW-0333P 16.2.1]*

4.2.2 Conditions Adverse to Quality

4.2.2.1 The QA organization shall concur with the proposed remedial action to ensure that QA program requirements are satisfied. *[DOE/RW-0333P 16.2.3.C]*

4.2.2.2 The QA organization shall verify implementation of corrective actions taken for all reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete. *[DOE/RW-0333P 16.2.5]*

4.2.3 Significant Conditions Adverse to Quality

4.2.3.1 Significant conditions adverse to quality shall be evaluated for a stop work condition by the QA organization to determine if stopping work is warranted. *[DOE/RW-0333P 16.2.4.C]*

4.2.3.2 QA management shall issue *stop work orders* (see def.) to responsible management after a stop work condition has been identified. *[DOE/RW-0333P 16.2.4.C. 1]*

4.2.3.3 The QA organization shall concur with the proposed corrective action, including remedial action, the root cause, and actions taken to prevent recurrence, to ensure that QA program requirements are satisfied. *[DOE/RW-0333P 16.2.4.F]*

4.2.3.4 QA management shall take appropriate action to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality. *[DOE/RW-0333P 16.2.4.C.2]*

5. DEFINITIONS

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

condition adverse to quality

corrective action

employee concern

management assessments

nonconformance

quality assurance records

remedial action

responsible manager

root cause

significant condition adverse to quality

stop work order

surveillances

testing

verification

6. REFERENCES

ASME NQA-1-1997, Quality Assurance Program Requirements For Nuclear Facilities

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

10 CFR 830 Subpart A, Quality Assurance

7. APPENDICES

APPENDIX A

16.1 Basis

Source	Citation	Requirement	Comments
ASME NQA-1, 1997, Quality Assurance Program Requirements For Nuclear Facilities, Requirement 16	100 1s	4.1.1.1	Consensus Requirement (CR)
NQA-1-1997, Requirement 16	100 2s	4.1.1.2	CR
NQA-1-1997, Requirement 16	100 3s	4.1.4.2	CR
NQA-1-1997, Requirement 16	100 4s	4.1.5.1	CR
Company Imposed Requirement	N/A	4.1.1.3	Company Imposed Requirement (CIR)
Company Imposed Requirement	N/A	4.1.1.4	CR
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10	16.2.1	4.2.1.1	Specific Requirement (SR)
DOE/RW-0333P	16.2.2.A	4.1.2.1	CR
DOE/RW-0333P	16.2.2.B	4.1.2.2	SR
DOE/RW-0333P	16.2.2.B.1	4.1.2.2.A	SR
DOE/RW-0333P	16.2.2.B.2	41.2.2.B	SR
DOE/RW-0333P	16.2.3.A	4.1.3.1	CR
DOE/RW-0333P	16.2.3.B	4.1.3.2	CR
DOE/RW-0333P	16.2.3.C	4.2.2.1	SR
DOE/RW-0333P	16.2.4.A	4.1.4.1	CR
DOE/RW-0333P	16.2.4.B	4.1.4.2	CR
DOE/RW-0333P	16.2.4.C	4.2.3.1	SR
DOE/RW-0333P	16.2.4.C.1	4.2.3.2	SR
DOE/RW-0333P	16.2.4.C.2	4.2.3.4	SR
DOE/RW-0333P	16.2.4.D	4.1.4.3.A	CR
DOE/RW-0333P	16.2.4.E.1s	4.1.4.3.B	CR
DOE/RW-0333P	16.2.4.E.2s	4.1.4.3.C	CR
DOE/RW-0333P	16.2.4.F	4.2.3.3	SR
DOE/RW-0333P	16.2.5	4.2.2.2	SR
DOE/RW-0333P	16.2.6.A	4.1.6.1	CR
DOE/RW-0333P	16.2.6.B	4.1.6.2	CR
DOE/RW-0333P	16.2.6.C	4.1.6.3	CR
DOE/RW-0333P	16.2.6.D	4.1.6.4	CR
DOE/RW-0333P	16.2.6.E	4.1.6.5	CR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.7.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements